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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/592,912

12/14/2007

Xiu-Min Li

2005577-0009

5719

24280 7590 08/24/2009
CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER

WINSTON, RANDALL O

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

08/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary	Application No.	Applicant(s)	
	10/592,912	LI ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0709</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of the receipt and entry of the amendment filed on 05/19/2009.

Claims 1-14 have been examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (Derwent ACC-NO 2002-217632 or CN 1327805, see abstract) in view of Hwange et al. (US 6,869,621), Prakash et al. (US 20040103908) and Houck et al. (US 20030130200) for the reasons set forth in the previous OFFICE ACTION which are restated below.

Applicant claims a herbal formulation and method for treating and/or lessening the severity of asthma, wherein said formulation consist of Ku-Shen (i.e. sophora root), Ling-zhi (i.e. Reishi), Gan-Cao (i.e. licorice), corticosteroid, bronchodilator (i.e. inhaled) and a pharmaceutical carrier.

Liu teaches a composition (i.e. a pharmaceutical composition) containing Ku-Shen (i.e. sophora root) and a pharmaceutical carrier (i.e. the pharmaceutical could be water) to treat asthma. (see, e.g abstract). Yang, however, does not teach the other

Art Unit: 1655

claimed active ingredients such as Ling-zhi (i.e. Reishi), Gan-Cao (i.e. licorice), corticosteroid, bronchodilator (i.e. inhaled) within Liu's composition to treat asthma.

Hwange beneficially teaches that Ling-zhi (i.e. reishi) treats asthma (see. e.g. column 8 lines 4-12).

Prakash beneficially teaches Gan-Cao (i.e. licorice) treats asthma (see. e.g. paragraph 008).

Houck beneficially teaches corticosteroid and bronchodilator (i.e. an inhaled bronchodilator) treat asthma (see. e.g. paragraph 0005 and 0007).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Liu's herbal formulation to include the other claimed active ingredients as taught by Hwange, Prakash and Houck within Liu's herbal formulation whereby the above cited combined reference teaching as a whole would create the claimed herbal formation and/or claimed method comprising of the claimed active ingredients to treat asthma in a subject in need thereof. Moreover, when the same combined herbal formation as a whole as the claimed invention's herbal formulation is administered to a subject in need thereof to treat asthma, the same combined herbal formulation as a whole would intrinsically have the same claimed functional effects within a subject in need thereof body (i.e. the functional effect of suppressing GATA-3 in a subject in need thereof and/or suppressing the activation of memory Th2 cells in a subject in need thereof) as the claimed inventions. Furthermore, as discussed in MPEP Section 2114.06, "it is *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same

Art Unit: 1655

purpose (i.e. to treat asthma in a subject in need thereof), in order to form a third composition to used for the same purpose.” Moreover, the adjustment of other conventional working conditions (e.g. determining suitable amounts/ranges of each active ingredient within the claimed composition), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant arguments have been fully considered but they are not deemed persuasive. Applicant argues that one skilled in the art of medicinal herbal formulations would not simply conclude that a single component of an eight component formulation could be used successfully for the same therapeutic purpose as the more complex formulation. Moreover, Applicant argues that the Declaration that includes Exhibit A filed on 05/19/2009 and Applicant's working examples clearly establishes that the combination of ingredients has a synergistic effect.

Although Applicant argues that one skilled in the art of medicinal herbal formulations would not simply conclude that a single component of an eight component formulation could be used successfully for the same therapeutic purpose as the more complex formulation, Applicant argument is not found persuasive because since the other cited secondary references are cited by examiner to remedy Liu's deficiencies, it

Art Unit: 1655

would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Liu's herbal formulation to include the other claimed active ingredients as taught by Hwange, Prakash and Houck within Liu's herbal formulation whereby the above cited combined reference teaching as a whole would create the claimed herbal formation and/or claimed method comprising of the claimed active ingredients to treat asthma in a subject in need thereof. Furthermore, as discussed in MPEP Section 2114.06, "it is *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. to treat asthma in a subject in need thereof), in order to form a third composition to used for the same purpose."

Moreover, although Applicant argues that the Declaration that includes Exhibit A filed on 05/19/2009 and Applicant's working examples clearly establishes that the combination of ingredients has a synergistic effect, Applicant argument is not found persuasive because it appears to examiner that applicant has not claimed any specific effective amounts and/or ranges of active ingredients within its claimed composition of claims 1-14 to determine whether applicants' claimed composition invention demonstrates unexpected results and synergism. What specific effective amounts and/or ranges of active ingredients within applicants' claimed composition of claims 1-14 (i.e. especially in independent claims 1) produce unexpected results and synergism?

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1655

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655